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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,976	01/16/2002	Derek J. Hei	282172000902	3174

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EXAMINER
NAFF, DAVID M

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/051,970	Hei et al
Examiner	**Group Art Unit**
Haff	1657

—The MAILING DATE f this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 2/27/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-54 is/are pending in the application.

Of the above claim(s) 10-24 + 27-54 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9, 25 + 26 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7 + 8 filed 6/13 + 9/3/02

☒ Notic of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Oth r _____

Office Action Summary

In a response of 2/27/03 to a restriction requirement of 1/27/03, applicants elected without traverse Group I claims 1-9, 25 and 26.

Claims 10-24 and 27-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 11 filed 2/27/03.

Claims examined on the merits are 1-9, 25 and 26.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by the preamble of claim 1 requiring treating a blood product containing a nucleic acid-containing pathogen to be inactivated, and not inactivating the pathogen in the steps carried out. The steps of claim 1 require removing free psoralen and low molecular weight psoralen photoproducts from a blood product, and nowhere recite a step of inactivating a nucleic acid-containing pathogen as required in the claim preamble.

The claims are further confusing in that the meaning and scope of "psoralen photoproducts" is uncertain.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wollowitz et al in view of Tsyurupa et al (193 on form 1449) and Davankov et al (110 on form 1449).

Method claims 1-9 are drawn to removing free psoralen and low molecular weight psoralen photoproducts from blood products by contacting a blood product containing free psoralen and low molecular weight psoralen photoproducts with a hypercrosslinked resin to remove the free psoralen and low molecular weight psoralen photoproducts. Claims 25 and 26 require blood products resulting from the method.

Wollowitz et al disclose adding psoralen compounds to inactivate pathogens in blood products, or blood products in synthetic media (col 1, line 17, and col 3, line 41) containing phosphate (col 5, line 29), irradiating and then removing free psoralen compounds from the blood with various adsorptive materials (col 53, lines 42-64) including Amberlite XAD-4 (col 53, line 50).

Tsyurupa et al and Davankov et al disclose using hypercrosslinked polystyrene-divinylbenzene copolymers for sorption and removal of a variety of organic compounds from aqueous mediums. The hypercrosslinked copolymers have exceptional high adsorption capacity. For example, see Tsyurupa et al (page 69, right col, lines 14-17, and page 70, left col, lines 6-10).

It would have been obvious to substitute for the Amberlite XAD-4 adsorbent resin of Wollowitz et al, the hypercrosslinked polystyrene-divinylbenzene copolymer taught by Tsyurupa et al and Davankov et al for the expected advantage of the hypercrosslinked copolymer providing exceptional adsorption capacity. Since both Amberlite XAD-4 and the hypercrosslinked copolymer are polystyrene-divinylbenzene copolymers and are essentially the same except for hypercrosslinking, it would have been expected that the hypercrosslinked copolymer would provide the sorption function of Amberlite XAD-4 required by Wollowitz et al of removing free psoralen compounds from treated blood or synthetic blood media. Blood products of claims 25 and 26 would have inherently resulted when using the hypercrosslinked polystyrene-divinylbenzene copolymer taught by Tsyurupa et al and Davankov et al in Wollowitz et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Wollowitz et al (5,593,823).

The claims are drawn to blood products resulting from the method described above.

Wollowitz et al is described above.

Blood products treated as disclosed by Wollowitz et al are the same as the blood products of the present claims. There is inadequate to establish that using a hypercrosslinked resin as claim produces a materially different blood product.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 25 and 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53-110 of copending Application No. 09/972,323 or claims 53-115 of copending Application No. 10/011,202. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention would have been obvious from the claims of the copending applications drawn to using an adsorbent material which can be a hypercrosslinked resin to remove psoralen compounds from blood products.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN
5/16/03

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651